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## NOTICE OF ALLOWANCE AND ISSUE FEE DUE

HM12/0418

SCIENCE & TECHNOLOGY LAW GROUP  
75 DENISE DRIVE  
HILLSBOROUGH CA 94010

APPLICATION NO.	FILING DATE	TOTAL CLAIMS	EXAMINER AND GROUP ART UNIT	DATE MAILED
09/469,197	12/21/99	042	LACOURCIERE, K	1635 04/18/01
First Named Applicant	PORTNOY, 35 USC 154(b) term ext. = 0 Days.			

TITLE OF INVENTION INTRACELLULAR DELIVERY VEHICLES

ATTY'S DOCKET NO.	CLASS-SUBCLASS	BATCH NO.	APPLN. TYPE	SMALL ENTITY	FEE DUE	DATE DUE
1	ZSP90-039-2	424-093.100	F09 UTILITY	YES	\$620.00	07/18/01

**THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED.**

**THE ISSUE FEE MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED.**

### HOW TO RESPOND TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

- A. If the status is changed, pay twice the amount of the FEE DUE shown above and notify the Patent and Trademark Office of the change in status, or
- B. If the status is the same, pay the FEE DUE shown above.

If the SMALL ENTITY is shown as NO:

- A. Pay FEE DUE shown above, or
- B. File verified statement of Small Entity Status before, or with, payment of 1/2 the FEE DUE shown above.

II. Part B-Issue Fee Transmittal should be completed and returned to the Patent and Trademark Office (PTO) with your ISSUE FEE. Even if the ISSUE FEE has already been paid by charge to deposit account, Part B Issue Fee Transmittal should be completed and returned. If you are charging the ISSUE FEE to your deposit account, section "4b" of Part B-Issue Fee Transmittal should be completed and an extra copy of the form should be submitted.

III. All communications regarding this application must give application number and batch number.

Please direct all communications prior to issuance to Box ISSUE FEE unless advised to the contrary.

**IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.**

**PATENT AND TRADEMARK OFFICE COPY**

# Notice of Allowability

Application No.

09/469,197

Examiner

Karen A. Lacourciere

Applicant(s)

PORTNOY ET AL.

Art Unit

1635

## -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance and Issue Fee Due or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 2/20/01.
2. ☒ The allowed claim(s) is/are 11-52.
3. ☐ The drawings filed on \_\_\_\_\_ are acceptable as formal drawings.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All    b) ☐ Some\*    c) ☐ None    of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

5. ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. **THIS THREE-MONTH PERIOD IS NOT EXTENDABLE FOR SUBMITTING NEW FORMAL DRAWINGS, OR A SUBSTITUTE OATH OR DECLARATION.** This three-month period for complying with the REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL is extendable under 37 CFR 1.136(a).

6. ☐ Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient. A SUBSTITUTE OATH OR DECLARATION IS REQUIRED.
7. ☐ Applicant MUST submit NEW FORMAL DRAWINGS
  - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review( PTO-948) attached
    - 1) ☐ hereto or 2) ☐ to Paper No. \_\_\_\_\_.
  - (b) ☐ including changes required by the proposed drawing correction filed \_\_\_\_\_, which has been approved by the examiner.
  - (c) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No. \_\_\_\_\_.

**Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.**

8. ☐ Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Any reply to this letter should include, in the upper right hand corner, the APPLICATION NUMBER (SERIES CODE / SERIAL NUMBER). If applicant has received a Notice of Allowance and Issue Fee Due, the ISSUE BATCH NUMBER and DATE of the NOTICE OF ALLOWANCE should also be included.

### Attachment(s)

- |                                                                                                        |                                                                                       |
|--------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------|
| 1 <input type="checkbox"/> Notice of References Cited (PTO-892)                                        | 2 <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)            |
| 3 <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                    | 4 <input checked="" type="checkbox"/> Interview Summary (PTO-413), Paper No. <u>9</u> |
| 5 <input type="checkbox"/> Information Disclosure Statements (PTO-1449), Paper No. _____               | 6 <input checked="" type="checkbox"/> Examiner's Amendment/Comment                    |
| 7 <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit of Biological Material | 8 <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance   |
|                                                                                                        | 9 <input type="checkbox"/> Other                                                      |

**WILLIAM N. PHILLIPS**  
**PATENT ANALYST**

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### EXAMINER'S AMENDMENT

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 11-52, drawn to a vaccine, classified in class 424, subclass 93.1.
  - II. Claims 53-64, drawn to a method of delivering a therapeutic agent, classified in class 435, subclass 252.1.
2. The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions; or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to methods and compositions which are not capable of use together and have different effects. For example, the vaccines and methods of Group I use antigenic agents and have the effect of eliciting an immune response, whereas the methods of Group II utilize therapeutic agents and have the effect of providing a therapeutic response.
3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

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4. During a telephone conversation with Richard Osman on 04-09-01 a provisional election was made without traverse to prosecute the invention of Group I, claims 11-52.

Claims 53-64 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

6. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Richard Osman on 04-09-01.

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7. The application has been amended as follows:

Claims 53-64 have been canceled.

Claim 40 has been amended to read:

40. (Twice amended) A method of introducing a foreign antigenic agent into a eukaryotic cell comprising the step of contacting the cell with [the bacterium of claim 11] a non-virulent bacterium comprising a first gene encoding a nonsecreted foreign functional cytolysin operably linked to a heterologous promoter which expresses the cytolysin in the bacterium, and a second gene encoding the foreign antigenic agent under conditions whereby the agent enters the cell.

### REASONS FOR ALLOWANCE

The following is an examiner's statement of reasons for allowance:

The prior rejections of record have been withdrawn in view of Applicant's arguments and amendments. The art search and of record does not teach or fairly suggest the vaccine compositions or methods claimed. Further, the Terminal Disclaimer filed on 10-31-00 obviates any rejection based on Double Patenting.

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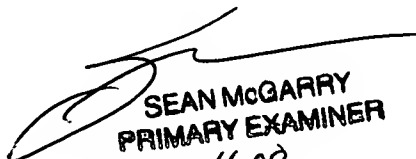
Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

***Conclusion***

Any inquiry concerning this communication should be directed to Karen A. Lacourciere at telephone number (703)308-7523.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached at (703) 308-0447. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

  
SEAN MCGARRY  
PRIMARY EXAMINER  
TC 1600

Karen A. Lacourciere  
April 9, 2001